



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10553, CMS-2746, CMS-2728, and CMS-10157]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Quality Assessment and Performance Improvement Programs, State Review of Accreditation Status, Medicaid Managed Care Quality Rating System, and Quality Strategy (QS) and Supporting Regulations; *Use:* Medicaid beneficiaries and stakeholders use the information collected and reported to understand the state’s quality improvement goals and objectives, and to understand how the state is measuring progress on its goals. States use this information to help monitor and assess the performance of their Medicaid managed care programs. This information may assist states in comparing the outcomes of quality improvement efforts and can assist them in identifying future performance improvement subjects. CMS uses this information as a part of its oversight of Medicaid

programs. *Form Number:* CMS-10553 (OMB control number: 0938-1281); *Frequency:* Yearly and occasionally; *Affected Public:* Private sector (business or other for profits) and State, Local, or Tribal Governments; *Number of Respondents:* 603; *Total Annual Responses:* 6,441; *Total Annual Hours:* 52,343. (For policy questions regarding this collection contact Barbara Dailey at 410-786-9012.)

2. *Type of Information Collection Request:* Reinstatement; *Title of Information Collection:* End Stage Renal Disease Death Notification; *Use:* The ESRD Death Notification form (CMS-2746) is completed by all Medicare-approved ESRD facilities upon death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. The ESRD Program Management and Medical Information System (PMMIS) has the responsibility of collecting, maintaining and disseminating, on a national basis, uniform data pertaining to ESRD patients and their treatment of care. All renal facilities approved to participate in the ESRD program are required by P.L. 95-292 to supply data to this system.

Federal regulations require that the ESRD Networks examine the mortality rates of every Medicare-approved facility within its area of responsibility. CMS-2746 provides the necessary data to assist the ESRD Networks in making decisions that result in improved patient care and in cost-effective distribution of ESRD resources. The data is used by the ESRD Networks to verify facility deaths and to monitor facility performance. The form is also used by health care planning agencies and researchers to determine survival rates by diagnoses. *Form Number:* CMS-2746 (OMB control number: 0938-0448); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 7,311; *Total*

Annual Responses: 92,023; Total Annual Hours: 46,011.50. (For policy questions regarding this collection contact Gequinicia Polk at 410-786-2305.)

3. *Type of Information Collection Request:* Reinstatement; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; Use: In accordance with section 226A of the law, the primary purpose of this form is to have a patient medically determined, by a physician, to have end stage renal disease for purposes of filing for Medicare benefits. The End Stage Renal Disease (ESRD) Medical Evidence (CMS-2728) is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life. The data reported on the CMS-2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries. Collection of these data are also necessary for entitlement of ESRD patients to Medicare benefits and also for the establishment and maintenance of a single, nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant. The data will enable individual practitioners and facilities to review, compare, and improve ESRD patient treatment methods, which will permit local Medical Review Boards to more effectively monitor utilization and quality of medical care. *Form Number:* CMS-2728 (OMB control number: 0938-0046); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit

Institutions); *Number of Respondents:* 7,311; *Total Annual Responses:* 138,000; *Total Annual Hours:* 103,500. (For policy questions regarding this collection contact Gequinicia Polk at 410-786-2305.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The HIPAA Eligibility Transaction System (HETS); *Use:* HIPAA regulations require covered entities to verify the identity of the person requesting PHI and the person's authority to have access to that information. Under the HIPAA Security rules, covered entities, regardless of their size, are required under 45 CFR Subtitle A, Subpart C 164.312(a)(2)(i) to "assign a unique name and/or number for identifying and tracking user identity." A 'user' is defined in 164.304 as a "person or entity with authorized access" Accordingly, the HIPAA Security rule requires covered entities to assign a unique name and/or number to each employee or workforce member who uses a system that receives, maintains or transmits electronic PHI so that system access and activity can be identified and tracked by user. This pertains to workforce members within small or large provider offices, health plans, group health plans, and clearinghouses. Federal law requires that CMS take precautions to minimize the security risk to the federal information system. Federal Information Processing Standards Publication(FIPS PUB) 101-2 Paragraph 11.7- Security and Authentication states that: "Agencies shall employ risk management techniques to determine the appropriate mix of security controls needed to protect specific data and systems. The selection of controls shall take into account procedures required under applicable laws and regulations." Accordingly, CMS requires that entities who wish to connect to the HETS application via the CMS Extranet and/or

Internet are uniquely identified. CMS is required to verify the identity of the person requesting the Protected Health Information (PHI) and the person's authority to have access to Medicare eligibility information. Furthermore, CMS requires that trading partners who wish to conduct eligibility transactions on a real-time basis with CMS provide certain assurances as a condition of receiving access to the Medicare eligibility information for the purpose of conducting real-time 270/271 inquiry/response transactions. *Form Number:* CMS-10157 (OMB control number: 0938-0960); *Frequency:* Yearly; *Affected Public:* Private Sector; Business or other for profits, Not-for-Profits Institutions; *Number of Respondents:* 1000; *Total Annual Responses:* 1000; *Total Annual Hours:* 250. (For policy questions regarding this collection contact Rupinder Singh at 410 786-7484.)

Dated: May 21, 2019.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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